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HONORABLE SALVADOR MENDOZA, JR.

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF WASHINGTON

JEREMY OLSEN,

Plaintiff,

v.

ALEX M. AZAR II, in his official capacity as the Secretary of the United States Department of Health and Human Services,

Defendant.

No. 2:20-cv-00374-SMJ

PLAINTIFF'S OPPOSITION TO MOTION FOR SUMMARY JUDGMENT

The Secretary's motion should be denied. As set forth in the Complaint and Mr. Olsen's own motion for summary judgment, Mr. Olsen is Type I diabetic whose diabetes led to kidney failure and a kidney transplant. Mr. Olsen was prescribed a continuous glucose monitor (CGM) to help control his diabetes and

protect the transplanted kidney. Mr. Olsen's claim for continuous glucose monitor (CGM) coverage was denied on the grounds that a CGM is not "primarily and customarily used to serve a medical purpose." That position is so ridiculous that four United States District Courts have rejected it and further ordered the Secretary to pay attorney's fees incurred in litigating the issue. Like every other court to consider it, this Court should reject the Secretary's motion.

BACKGROUND

Factual Background

Plaintiff Jeremy Olsen is a Type I diabetic who also suffers from "brittle" diabetes with hypoglycemic unawareness. ECF No. 2, Ex. 5 at 3. Mr. Olsen's diabetic condition resulted in damage to his kidneys, leading to kidney failure, and necessitating a kidney transplant. Both to address his underlying diabetes and to protect his transplanted kidney from damage as a result thereof, Mr. Olsen's treating physician prescribed a continuous glucose monitor (CGM). *Id*. A CGM continuously tests glucose levels, alerts the user of out of range values, and, in Mr. Olsen's case, communicates with an insulin pump to automatically adjust insulin dosage. Incredibly, Mr. Olsen's claim for Medicare coverage for his CGM has been rejected by the Secretary on the grounds that a CGM is not "primarily and

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customarily used to serve a medical purpose" as set forth in CMS 1682-R. ECF No. 2, Ex. 7 at 8.

Procedurally, Mr. Olsen submitted his claim and it was denied. *See* ECF No. 2, Ex. 2. Mr. Olsen appealed (*i.e.*, "redetermination") and that was denied. *See* ECF No. 2, Ex. 3. Mr. Olsen appealed (*i.e.*, "reconsideration") and that was denied. *See* ECF No. 2, Ex. 4. Mr. Olsen appealed to ALJ Lambert who found that a CGM is "durable medical equipment" that is "primarily and customarily used to serve a medical purpose." *See* ECF No. 2, Ex. 5.

Through so called "own motion review", the Secretary appealed ALJ Lambert's decision to the Medicare Appeals Council (MAC). *See* ECF No. 2, Ex. 6. In a decision dated July 23, 2019, the MAC reversed ALJ Lambert and denied Mr. Olsen's claim on the grounds that a CGM is not "primarily and customarily used to serve a medical purpose" and is, therefore, not "durable medical equipment." *See* ECF No. 2, Ex. 7. In particular, the MAC rejected the decisions of two United States District Courts holding that a CGM is "primarily and customarily used to serve a medical purpose." Instead, the MAC relied on its own construction of "primarily and customarily used to serve a medical purpose" as set forth in CMS 1682-R that the Secretary illegally issued. Relying on the illegally issued CMS 1682-R, the MAC denied Mr. Olsen's claim.

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Legal Background

1. Standard of Review

Pursuant to 42 U.S.C. § 405(g), the factual conclusions of the Secretary (if supported by substantial evidence) are conclusive. For all other questions, the Secretary's conclusions should be evaluated using any standard available under the Administrative Procedure Act (*e.g.*, arbitrary and capricious, abuse of discretion, contrary to law, etc.). *See, e.g., Friedman v. Sebelius*, 686 F.3d 813, 826-7 (D.C. Cir. 2012) ("We therefore review the Secretary's decision to exclude the Appellants according to the arbitrary and capricious standard.").

As stated in *Motor Vehicle Mfg. Assoc. of the U.S. v. State Farm Automobile Insurance Co.*, 463 U.S. 29 (1983) with regard to the standard for arbitrary and capricious:

> [T]he agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the fact found and the choice made. In reviewing that explanation, we must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment. Normally, an agency rule would be arbitrary and capricious if the agency has relied on factor which Congress has not intended it consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Id. at 43. (internal citations and quotations omitted).

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2. Statutory Construction

With regard to *statutory* construction, the first step is to employ all the traditional rules of construction. *See, e.g., SAS Inst., Inc. v. Iancu*, 138 S.Ct. 1348, 1358 (2018). Only after doing so, if the Court is unable to discern the meaning and the statute is ambiguous, should the Court consider whether *Chevron* deference should apply to any proposed construction of the statute. *See Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-3 (1984) ("If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."). Even if a statute is ambiguous, a court should only accord deference to "reasonable" constructions offered by an agency. *Id*. at 844. "Where the agency interprets a statute in a way that flatly contradicts Congress's express purpose, the court may – indeed, must – intervene and correct the agency." *See Common Cause v. Fed. Elec. Comm'n*, 692 F.Supp. 1391, 1396 (D.D.C. 1987).

3. Regulatory Construction

With regard to *regulatory* construction, again, the first step is to employ all the traditional rules of construction. *See Kisor v. Wilkie*, 139 S.Ct. 2400, 2415-6 (2019). If, after doing so, the regulation is not ambiguous, then that is the end of the inquiry and the Court should give effect to the regulation. As stated in *Kisor*:

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> First and foremost, a court should not give *Auer* deference unless the regulation is genuinely ambiguous. If uncertainty does not exist, then there is no plausible reason for deference. The regulation just means what it means – and the court must give it effect, as the court would any law.
>
> * * *
>
> But if the law gives an answer – if there is only one reasonable construction of a regulation – then a court has no business deferring to any other reading, no matter how much an agency insists it would make more sense. Deference in that circumstance would "permit the agency, under the guise of interpreting a regulation, to create a *de facto* new regulation."

Id. (internal citations omitted). Conversely, if the regulation is still ambiguous, deference to "reasonable" constructions offered by an agency may be appropriate in certain circumstances. *Id*. at 2415-6 ("If genuine ambiguity remains, moreover, the agency's reading must still be 'reasonable'."). Constructions which are arbitrary, capricious, or manifestly contrary to a statute or regulation are not reasonable. *See Chevron*, 467 U.S. at 844.

4. Durable Medical Equipment

Medicare covers "durable medical equipment." Pursuant to 42 U.S.C. § 1395x(n), "durable medical equipment" is not defined, except by a non-exhaustive list of examples. One specific example cited is "blood glucose monitors."

The Secretary has, after proper notice and opportunity for public comment, issued regulations further setting forth a five-part test to determine whether

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equipment is "durable medical equipment." *See* 42 C.F.R. § 404.202. Equipment is considered "durable medical equipment" if it:

a) Can withstand repeated use;
b) Has an expected life of at least 3 years;
c) Is primarily and customarily used to serve a medical purpose;
d) Generally is not useful to an individual in the absence of illness or injury; and
e) Is appropriate for use in the home.

The Secretary clarified this test, also with proper notice and opportunity for comment, with respect to multi-component systems, like the Medtronic MiniMed 530G System. (76 Fed. Reg. 70291).

5. CMS 1682-R/LCD L33822

Without prior notice and comment, on January 12, 2017, the Secretary issued CMS 1682-R. As stated, "CMS Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation." ECF No. 2, Ex. 9 at 1. There, the Secretary maintained, incorrectly on the facts, that any CGM which did not completely replace finger sticks was "precautionary" and not covered. The Secretary asserted that if the reading from a CGM sensor had to be confirmed with a finger stick prior to making a treatment decision, the CGM was not "primarily and customarily used to serve a medical purpose." *Id.* at 6-7.

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Conversely, CGMs which do replace finger sticks the Secretary labeled "therapeutic" and considered covered. By its own terms, CMS 1682-R was effective as of the very date it issued – *i.e.*, January 12, 2017. As described in the Council's decision, this is a "coverage policy for CGM's and ancillary equipment." *Id.* at 9. Effective the same day, and also without notice and comment, CMS 1682-R was incorporated into LCD L33822.

6. Prior Litigation

The issue of whether a CGM qualifies as durable medical equipment has been litigated multiple times. In sum, the Secretary has refused to cover CGMs on the grounds: 1) that CGMs do not comply with the non-statutory/non-regulatory term "precautionary"; and/or 2) that CGMs do not serve a "primary medical purpose" (as opposed to the regulatory phrase "primarily … used to serve a medical purpose"). Those bases for denying CGM claims have been litigated in four district court cases.

In *Whitcomb v. Azar*, Case No. 17-cv-14 (E.D. Wisc. Oct. 26, 2017) (Jones, J.), *Bloom v. Azar*, 2018 WL 583111 (D. Vt. January 29, 2018) (Crawford, J.) and *Lewis v. Azar*, 2018 WL 1639687 (D. Mass. April 5, 2018) (Gorton, J.), and *Zieroth v. Azar*, 2020 WK 5642614 (N.D. Cal. Sept. 22, 2020) (Chesney, J.) the district courts found that the Secretary's claim that a CGM is not "primarily and

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customarily used to serve a medical purpose"/was "precautionary" was erroneous, not supported by substantial evidence and/or was arbitrary and capricious. In each case, the court determined that CGMs are entitled to coverage as durable medical equipment and ordered the Secretary to provide CGM coverage. Each of those decisions is final. Moreover, in each of those cases, the court further found that the Secretary's position lacked "substantial justification" and ordered the Secretary to pay the plaintiffs' attorney fees for having to litigate the issue.

In addition, the Secretary's own Civil Remedies Division concluded that the Secretary's claim that a CGM was not covered as "precautionary" did not meet the "reasonableness standard." *See Lewis v. Azar*, DAB No. CR4596, WL 2851236 at *18 (2016) (reversed on other grounds).

DISCUSSION

As set forth in Mr. Olsen's co-pending motion for summary judgment, this Court should deny the Secretary's motion (and grant Mr. Olsen's) on the grounds that CMS 1682-R (used to deny Mr. Olsen's claim) issued illegally. Pursuant to 42 U.S.C. § 1395hh, no rule which fails to comply with its notice and comment provisions "shall take effect." Given that the Secretary does not deny that the Secretary failed to comply with those provisions before issuing CMS 1682-R and that CMS 1682-R issued illegally, the Court should deny the Secretary's motion,

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grant, Mr. Olsen's and remand this case with instructions to cover Mr. Olsen's claim. No further analysis is necessary.

To the extent the Court goes beyond the sheer illegality of CMS 1682-R, then the Secretary's denial of Mr. Olsen's claim is not supported by substantial evidence, is arbitrary and capricious, etc.

The Secretary had, prior to issuing CMS 1682-R without notice and comment, issued regulations, after proper notice and comment, clarifying what is considered "durable medical equipment" including a five-part test. *See* 42 C.F.R. § 404.202. In CGM cases, including this one, the Secretary has contended that CGMs are not "primarily and customarily used to serve a medical purpose" but has not disputed that CGMs meet the other four factors.

With regard to "primarily and customarily used to serve a medical purpose", as noted in *Kisor*, the first step is to determine whether the provision is "genuinely ambiguous." *Kisor*, 139 S.Ct. at 2415-6. If the provision is not ambiguous, deferring to any proposed construction by the agency "would permit the agency, under the guise of interpreting a regulation, to create a *de facto* new regulation." *Id.*

Here, neither the MAC decision nor CMS 1682-R contend that "primarily and customarily used to serve a medical purpose" is ambiguous and, indeed, it is

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not. As the court in *Whitcomb* noted, "The regulation defining durable medical equipment, as that term is used in the Act, is clear on its face." *Whitcomb,* at 11. Thus, because the provision is not ambiguous, "the court must give it effect[.]" *Id.* Here, again, there is simply no evidence that a CGM is *not* "primarily and customarily used to serve a medical purpose." Indeed, the Secretary's conclusion otherwise is arbitrary and capricious. That should be the end of the inquiry.

Moreover, to the extent that the Court is even willing to consider the Secretary's proposed construction of "primarily and customarily used to serve a medical purpose", that construction is unreasonable. As the courts in *Whitcomb, Bloom*, *Lewis,* and *Zieroth*, concluded, the Secretary has never offered a construction of the phrase that makes any sense or a reason to import the non-statutory/regulatory term "precautionary" (or even a logical meaning for that term).

To the extent the Secretary attempts to recast 42 C.F.R. § 404.202 to be limited to "serve a primary medical purpose" – rather than the actual language of "primarily and customarily used to serve a medical purpose" - again, as the courts in *Whitcomb, Bloom*, and *Lewis*, and *Zieroth* found, that proposed construction is unreasonable, and arbitrary and capricious. The Secretary's position simply flies in the face of the regulation and constructions which contradict the regulation are

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unreasonable. *See, e.g.*, *Common Cause*, 692. F,Supp. at 1396. It is to be expected, and the Secretary's prior regulations respecting multi-component systems confirm, that many medical conditions will require multi-component durable medical equipment to treat. And there is nothing in the statute or regulations limiting coverage to a single piece of durable medical equipment that, alone entirely treats and illness or injury. Stated alternatively, there is not substantial evidence to support the Secretary's conclusion otherwise.

Put simply, the idea that a CGM is not "primarily and customarily used to serve a medical purpose" is utterly baseless and at odds with reality. This is especially so in this case, where it is undisputed that one purpose of the CGM is to protect Mr. Olsen's transplanted kidney. The sheer non-sensical nature of the result is one indication that the Secretary's position is without merit.

CONCLUSION

For the reasons set forth above, the Court should deny the Secretary's motion, grant Mr. Olsen's motion, and remand this case (pursuant to 42 U.S.C. § 405(g)) with instruction cover Mr. Olsen's claim.

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Dated this 28th day of December, 2020.

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By: *s/ Casey M. Bruner*

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CERTIFICATE OF SERVICE

I hereby certify that on the 28th day of December 2020,

1. I caused to be electronically filed the foregoing PLAINTIFF'S OPPOSITION TO MOTION FOR SUMMARY JUDGMENT with the Clerk of the Court using the CM/ECF System which will send notification of such filing to the following:

James.Bickford@usdoj.gov

2. I hereby certify that I have caused to be mailed by United States Postal Service the foregoing document to the following non-CM/ECF participants at the addresses listed below:

Jeffrey Blumenfeld
Lowenstein Sandler LLP
2200 Pennsylvania Avenue, NW, Suite 500E
Washington, DC 20037

3. I hereby certify that I have mailed by United States Postal Service the foregoing document to the following CM/ECF participants at the address listed below: **None.**

4. I hereby certify that I have hand-delivered the foregoing document to the following participants at the addresses listed below: **None.**

s/ Casey M. Bruner
Casey M. Bruner, WSBA #50168

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